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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,616	09/30/2003	Mina Chow	5618P3611	7937

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EXAMINER	
GRAY, PHILLIP A	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
12/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,616	CHOW ET AL.	
	Examiner	Art Unit	
	Phillip Gray	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-10,12-28,115-122,127,128 and 132* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-10,12-28,115-122,127,128 and 132* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's communication of 9/29/2010. Currently amended claims 1, 4-10, 12-28, 115-122, 127, 128 and 132 are pending and rejected below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

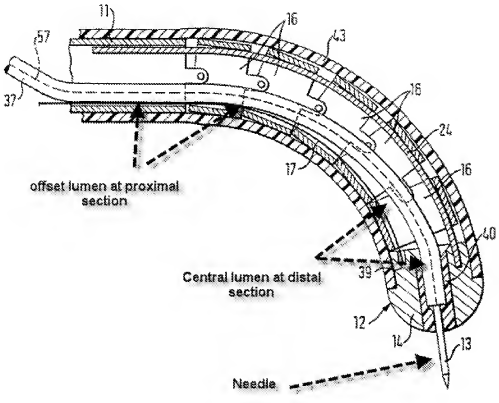
Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ham et al. (U.S. Patent Number 5,456,667) in view of Fritzsch (U.S. Patent 5,441,499).

Ham discloses a deflectable catheter assembly (see figure 1) with a catheter shaft (internal compartment of 26 or 11) with a proximal section (bottom) and distal (top), a tendon (13) disposed within a first lumen (internal area of 17) which is approximately centrally located at the proximal section (note lumen position is central as it approaches near 44) and at the distal end the lumen is off center (note lumen position is off center as it approaches near top area and numeral 17), and the tendon deflects the catheter distal section, and a Catheter handle (40) coupled to the shaft, including a first control mechanism (such as 38/39/41 or 43).

Concerning the claim language of "said catheter proximal section having a length greater than that of the catheter distal section" it is examiners position that Ham does have a proximal section length greater then the distal section length. The claim fails to specify where the proximal and distal sections start and end. The only requirements are that the distal is more flexible then the proximal. For example one analysis of Ham could be the first 4 inches of the proximal end of the Ham device is the "proximal section" and the last inch of the Ham device is the "distal section". It is recommended that applicant specify in greater detail what constitutes the exact metes and bounds of the "proximal" and "distal" catheter sections (i.e. where do they start and end and do they transition directly into the other or is there a transition region, ect.).

Fritzsch discloses a needle (13) disposed within a second lumen (37/57) being located off-center within the catheter shaft at the proximal section and located approximately centrally located at the distal section (see figures 1, 2, 3, and 9 for examples). Note Fritzsch marked up figure 3 below.

Fig. 3



Ham discloses the claimed invention except for a needle disposed within a second lumen being located off-center within the catheter shaft at the proximal section and located approximately centrally located at the distal section. Fritzsch teaches that it is known to use a needle within a lumen being located off center in the proximal section and approximately centrally located at the distal section as set forth in paragraphs at columns 4-6 and shown in figures 1-3 and 9, to provide a cutting probe needle in a

pivoting catheter for direct view of the surgical operation for cutting or coagulating a body vessel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Ham with a needle and lumen cental at the distal section and off-center at the proximal section as taught by Fritzsch, since such a modification would provide the system with for a needle disposed within a second lumen being located off-center within the catheter shaft at the proximal section and located approximately centrally located at the distal section for providing provide a cutting probe needle in a pivoting catheter for direct view of the surgical operation for cutting or coagulating a body vessel.

Claims 4-10, 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster in view of Ham in further view of Fritzsch.

Webster discloses the claimed invention except for the lumen in the catheter shaft which is centrally located in the proximal end and off center in the distal end. Ham in view of Fritzsch teaches that it is known to use the needle and lumen in the catheter shaft which is centrally located in the proximal end and off center in the distal end as set forth in paragraphs at column 5 lines 9 through 66 to provide an efficient and centrally located means to control the device (at the handle) while deflecting or moving the catheter tip in a given direction (near distal end). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Webster with the lumen in the catheter shaft which is centrally located in the proximal end and off center in the distal end as taught by Ham in view of Fritzsch,

since such a modification would provide the system with preferred lumen configuration for providing an efficient and centrally located means to control the device (at the handle) while deflecting or moving the catheter tip in a given direction (near distal end).

WEBSTER discloses a deflectable catheter assembly comprising: a catheter shaft (interior of element 91); a tendon (31) disposed within a first lumen of said catheter shaft, said first lumen being approximately centrally located within said catheter shaft at said catheter proximal section (as in figure 8 for example) and said first lumen located off-center of said catheter shaft at said catheter distal section (as in figure 6A and 6b), said tendon being able to deflect said catheter distal section when being pulled on (as in figures 1 and 7); and a catheter handle (14) coupled to said catheter shaft, said catheter handle including a first control mechanism (63 for example) to control said tendon, and slip bands (33). Webster also comprises a needle (not shown but inherent, see paragraphs beginning at column 3, line 16), or a plurality of needles, disposed within a lumen of said catheter shaft (not shown but in fifth lumen and an inherent feature of Webster, also concerning the limitations of claims 10-11).

Concerning claims 5 and 6, Webster further comprises, an axial spine (91 or 92) disposed around and over a first section of said tendon, said first section being substantially aligned with said catheter proximal section, said axial spine to resist axial compression along said catheter proximal section (See figure 11), and a flexible tendon sheath (95) coupling to said axial spine, said flexible tendon sheath extending a second section of said tendon and said second section being substantially aligned with said catheter distal section (see figures 1-14)

Concerning claim 8 and 9, Webster discloses a tip electrode (29) located at the tip of said catheter distal section and coupled to a conductive lead that extends out of said catheter shaft and at least one additional electrode (28). Webster discloses a deflectable catheter fully capable of all flexibility requirements in claims 16-17 (see figure 7). Further, Webster discloses a pre-shaped guide sheath (92, 91) disposed around said catheter shaft that is fully capable of satisfying all functional, structural, and operational limits of the claims as written.

Claims 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster in view of Ham in view of Fritzsch in further view of Edwards et al. (U.S. Patent Number 6,254,598).

Webster discloses the claimed invention except is silent as to the medical device comprising a needle or a plurality of needles with at least one inflatable balloon coupling to said plurality of needles (and with a divergent angle), tube mechanism with needle stop disposed within a lumen of a catheter shaft being extendable from and retractable into the catheter distal section and a control in the catheter handle. Edwards teaches that it is known to use the needles/balloon mechanism (figure 8) as set forth in abstract and specifically columns 5-12 to provide a unique and direct medical treatment operation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter as taught by Webster with the needles/balloon mechanism as taught by Edwards, since such a modification would

provide the catheter with the needles/balloon mechanism for providing a unique and direct medical treatment operation.

Claims 115-122, 127-128, 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster in view of Hamin view of Fritzsch in further view of Edwards and in further view of Balbierz (U.S. Patent Number 6,770,070).

Webster in view of Ham in further view of Edwards discloses the claimed invention except for the using and coupling pressure sensors to a needle. Balbierz teaches that it is known to use and coupling pressure sensors to a needle as set forth in paragraphs beginning at column 12, line 39 to provide a specific diagnostic feedback mechanism to the catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter as taught by Webster in view of Ham in further view of Edwards with using and coupling pressure sensors to a needle as taught by Balbierz, since such a modification would provide the catheter with using and coupling pressure sensors to a needle for providing a specific diagnostic feedback mechanism to the catheter. Balbierz further discloses using and coupling pressure sensors to a needle that would be fully capable of satisfying all structural, functional, and operational claim limitations.

Concerning claims 132, Webster in view of Ham in further view of Edwards discloses the claimed invention except is silent about the needle made of a polymer material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the needle of a polymer material, since it has been

held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).*

Response to Arguments

Applicant's arguments with respect to claims 4-10, 12-28, 115-122, 127, 128 and 132, the remarks have been considered but are moot in view of the new ground(s) of rejection. Examiner is relying on the Fritzsch to teach the needle disposed within a second lumen that is off-center within the proximal section and approximately centrally located within the distal section. See rejection and figure above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/

Examiner, Art Unit 3767

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767